510(K) Summary
(21 CFR Part 807.92)

A. Submitter Information

Submitter's Name:	Theken Spine
Address:	283 E. Waterloo Akron, Ohio 44319
Telephone Number:	330-773-7677 x221
Fax Number:	330-773-7697
Contact Person:	Dale Davison
Date Prepared:	16 January 2007

APR 25 2007

B. Device Information

Trade Name:	Theken Vu Mesh Vertebral Body Replacement (VBR)
Common Name:	Vertebral Body Replacement Device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 888.3060)
Device Classification:	Class II (per 21 CFR 888.3060) Panel: Orthopedic, Product Code: MQP, Panel Code: 87
Predicate Device:	Theken Surgical LLC Reveal VBR System (K050058)
Comparative Devices:	DePuy-AcroMed, Inc.-Surgical Titanium Mesh System (K003043) Synthes (USA)- SynMesh Spacer System (K003275) Encore Orthopedics, Inc.-Titanium Mesh (K032371) SIGNUS Medical LLC -Curved PEEK Tetris™ (K041888) SIGNUS Medical LLC - PEEK Tetris™ (K031757)
Material Composition:	PolyEtherEtherKetone (PEEK OPTIMA LT) per ASTM F2026. Tantalum per ASTM F560
Subject Device Description:	The Theken Vu Mesh VBR system is comprised of square footprint polymer cages with fenestrations axially and laterally. It includes toothed endplates, which are used in combination with optional spacer components to extend the range of the cage in smaller increments. The cages, spacers and endplates can be assembled in a variety of combinations to fit each individual patient's pathology. The toothed endplates engage with the superior and inferior endplates of the neighboring vertebral bodies to resist rotation and migration. The Vu Mesh cage may be used individually or in a pair depending on the surgical need, however, the device is always implanted with the mesh cage oriented vertically.

Theken Spine	Vu Mesh VBR	2/1/2007

Intended Use:

The Theken VU MESH VBR System is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or otherwise unstable vertebral body due to tumor or trauma (i.e. fracture).

The Theken VU MESH VBR System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. Bone graft material is recommended for packing into the interior opening of the device prior to implantation.

The Theken VU MESH VBR System is intended for use with supplemental internal spinal fixation systems, such as the Theken BodyForm Thoracolumbar Fixation System (K983622, Approved 12/98) or the Theken Coral Pedicle Screw System (K041592, Approved 9/04).

C. Substantial Equivalence

The technological characteristics of the Theken Vu Mesh VBR SYSTEM are similar to the following predicate devices:

1. REVEAL VBR System (K050058) manufactured by Theken Spine LLC and cleared by the FDA on May 17, 2005.
2. Surgical Titanium Mesh System (K003043) manufactured by DePuy-AcroMed, Inc. and cleared by the FDA on May 8, 2001.
3. SynMesh Spacer System (K003275) manufactured by Synthes (USA) and cleared by the FDA on April 23, 2001.
4. Titanium Mesh (K032371) manufactured by Encore Orthopedics, Inc and cleared by the FDA on February 12, 2004
5. Curved PEEK Tetris™ (K041888) manufactured by SIGNUS Medical LLC and cleared by the FDA on August 10, 2004.
6. PEEK Tetris™ (K031757), manufactured by SIGNUS Medical LLC and cleared by the FDA on July 3, 2003.

Establishment of equivalence is based on similarities of intended use, design, and physical characteristics. All implants are used to treat the same conditions, have essentially the same precautions and contraindications for use, and have equivalent potential for complications. Based on the design concept, the use of established well known materials, feature comparisons, mechanical testing, indications for use, pre-production quality assurance planning and engineering analysis, Theken Spine believes that sufficient evidence exists to reasonably conclude that the Vu Mesh VBR System is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Theken Spine
c/o Mr. Dale Davison
Vice President of Engineering
283 East Waterloo Road
Akron, Ohio 44319

APR 25 2007

Re: K070381
Trade/Device Name: Vu Mesh VBR System
Regulation Number: 21 CFR §888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: March 30, 2007
Received: April 02, 2007

Dear Mr. Davison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

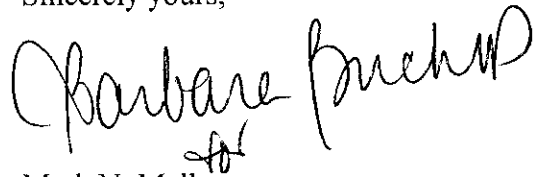
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070381
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Indications for Use

510(k) Number (if known):

Device Name: Vu MESH VBR System

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The Theken VU MESH VBR SYSTEM is indicated for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or otherwise unstable vertebral body due to tumor or trauma (i.e. fracture).

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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